REMARKS

I. Status of the Claims

Claims 15, 16 and 18-22 have been canceled. Claims 30-34 are now pending. No new matter has been introduced by this Amendment.

II. Claim Rejections – 35 U.S.C. § 102

The Examiner has rejected claim 34 under 35 U.S.C. 102(a) as allegedly being anticipated by WO 99/36050 ("Kelly et al."). Applicants respectfully traverse this rejection for the following reasons.

The invention of claim 34 relates to a method of treating and preventing sunburn on the skin of a mammal comprising the step of applying a skin care composition comprising a non-denatured soy product containing trypsin inhibitory activity and a stabilizing system. As discussed in the Specification, a "non-denatured soy product" is a soy product in which the processing for the derivation of such soy product (e.g., the temperature, extraction media) did not eliminate its protease inhibitory activity." Indeed, the non-denatured state of the soy product of this invention is measured by the presence of an intact soybean trypsin inhibitor (STI) protein. Specification page 7, lines 10-14. Example 11 of the Specification demonstrates the uniqueness of the compositions according the invention when compared to conventionally used soy-based products. As shown by Example 11, the soymilk-containing compositions of the invention are non-denatured and contain intact STI. In contrast, commercial soy-base product (Helena Rubinstein's Furture White Essence) did not contain intact STI and is therefore distinct from the non-denatured soy product of the claimed invention.

The Examiner relies upon Kelly et al. as teaching the use of soy extract for protecting skin from UV damage. The Examiner argues that the "recitation of 'non-denatured' soy product is inherent in the reference because soy beans are extracted without using enzymes and/or temperature." The Examiner also notes that Kelly et al. teaches that "soy or clover may be extracted with a mixture of organic solvents (such as ethanol, chloroform, acetone, ethyl acetate and the like) and water. The ratio of solvent to water may be from 0.1 to 99.9%, preferably 40% to 60%." See page, 11, lines 23-27. The Examiner then concludes that it is

"highly unlikely that 0.1% of ethanol in water will cause protein denaturing." For these reasons, the Examiner maintains that Kelly et al. anticipates claims 22 and 34. Applicants respectfully disagree.

Applicants respectfully point out, as the Examiner is well aware, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See M.P.E.P. § 2131. Further, when the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, in order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." See, e.g., *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 °C did **not** describe the claimed range of 330-450°C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350°C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure of a range is no more a disclosure of the end points of the range than it is each of the intermediate points." *Id.* at 1000, 78 USPQ2d at 1424.

Here, Applicants note that Kelly et al. completely fails to teach with any specificity a non-denatured soy product containing trypsin inhibitory activity. In fact, Kelly et al. specifically teaches that for extraction of soy or clover, the preferred ratio of solvent to water is 40% to 60%. Even if one of ordinary skill in the art would have been motivated to use 0.1% solvent one would not arrive at the claimed invention. As demonstrated in the Declaration of Miri Seiberg filed December 4, 2009 ("2009 Seiberg Declaration"), a ratio of organic solvent in water as low as 0.1% would not effectively facilitate the intent and purpose of the Kelly et al. compositions. Indeed, a much higher organic solvent content is necessary to extract isoflavones from soy. Accordingly, Kelly et al. simply fails to anticipate claim 34.

The Examiner also argues that "Applicant has not differentiated between soy beans that have or do not have this property by their structure of process steps." The attached Declaration of Yaping Hu demonstrates the difference between the soy products of the claimed invention, *i.e.,* non-denatured soy, and the soy products vaguely disclosed by Kelly et al. As demonstrated therein, the Kelly et al. soy products do not exhibit trypsin inhibition

activity. For these reasons, Kelly et al. fails to disclose the claimed invention with sufficient specificity to constitute anticipation and the rejection should be withdrawn. Further, Kelly et al. fails to render the presently claimed invention obvious as there is simply no teaching or suggestion of a non-denatured soy product containing trypsin inhibitory activity as clearly demonstrated by the Declaration of Yaping Hu. Accordingly, Applicants respectfully request withdrawal of this rejection.

III. Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected claims 30-33 under 35 U.S.C. 103(a) as allegedly being obvious over JP 5-320061, translation of record ("Tokuyama") in view of JP 62-36304, of record ("Mizue"). Applicants respectfully traverse this rejection for the following reasons.

The claimed invention relates to non-denatured soy product containing compositions useful for the care of the skin, such as, evening skin tone, treating acne, evening the texture of the skin, increasing the elasticity and firmness of the skin, reducing the shine and oiliness of the skin and treating cellulite in the skin and treating. Tokuyama relates to an oxygen elimination agent, using legumes as the raw material that acts as an anti-oxidant and is safe and inexpensive and that can be used in broad range of fields such as medicinal drugs, food products and cosmetic products. The Examiner takes the position that Tokuyama in Examples 2 and 3 teach "the same extraction method as disclosed in the instant application." Further, the Examiner argues that because Tokuyama recites that "black soybeans possess tyrosinase inhibitory activity in Table 1, the soy beans recited in Tokuyama are not denatured and inherently possess STI's protease inhibitory activity." Office Action, p. 9. Applicants respectfully disagree.

Tokuyama teaches two groups of legume extracts: (A) organic extractions of legumes using 90% alcohol (Examples 2 and 3 of Tokuyama) and (B) aqueous extracts of legumes which are boiled (Example 1 of Tokuyama). Both therefore are denatured and do not possess trypsin inhibitory activity. As shown by the Declaration of Yaping Hu soybeans extracted with 60% ethanol did not have trypsin inhibition activity. Accordingly, the extraction with an even higher percentage of solvent (90%) would clearly cause loss of trypsin inhibitory activity.

Further, Applicants note that the discussion of tyrosinase inhibitory activity is in Table 5 not Table 1 of Tokuyama. Table 5 uses the product obtained in Example 1 which is dry red beans pulverized followed by extraction by **boiling** for 5 minutes which would clearly cause denaturization. Further, the discussion in Table 5 of Tokuyama relied upon by the Examiner relate to **tyrosinase** inhibitory activity by the isoflavones. Tyrosinase inhibitory activity and trypsin inhibitory activity are not the same. Isoflavones inhibit tyrosinase. All soy extracts, denatured and nondenatured, contain isoflavones and therefore inhibit tyrosinase. However, only nondenatured soy extracts exhibit trypsin inhibitory activity. As set forth in the attached Declaration of Miri Seiberg and appended publications, isoflavones, not being proteins, cannot undergo denaturation. Further, the attached Declaration of Yaping Hu demonstrates that soy preparations prepared according to the present invention exhibit trypsin inhibition activity. In contrast, as also demonstrated by the Declaration of Yaping Hu, genistin and daidzin, two major soy isoflavones, do not have trypsin inhibition activity. Accordingly, the evidence of record, as a whole, clearly demonstrates that the legumes disclosed by Tokuyama are not "non-denatured soy products containing trypsin inhibitory activity."

The Examiner also relies upon Mizue as teaching stabilizing soy extracts in cosmetic compositions with preservatives. However, Mizue fails to remedy the fatal deficiency of Tokuyama. Adding preservatives to a composition that does not contain soy trypsin inhibitory activity, or which contains denatured proteins such as STI, will not resurrect the activity of the proteins which originally had such soy trypsin inhibitory activity.

For the reasons discussed above, Tokuyama and Mizue, taken alone or in combination, fail to teach or suggest the use of non-denatured soy products containing trypsin inhibitory activity in skin care compositions for evening skin tone, treating acne, evening the texture of the skin, increasing the elasticity and firmness of the skin, reducing the shine and oiliness of the skin and treating cellulite in the skin. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness and the rejection should be withdrawn.

IV. Conclusion

For the reasons set forth above, Applicants respectfully request withdrawal of all outstanding rejections. If the Examiner feels that a discussion with Applicants' representative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP0518/JPB. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 10-0750/JBP0518/JPB.

Respectfully submitted,

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January 10, 2011